U.S. Research Universities' Institutional Conflict of Interest Policies

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ABSTRACT: RESEARCH UNIVERSITIES RECEIVE INCREASING amounts of income from intellectual property, which makes institutional conflict of interest (ICOI) policies increasingly important. We analyzed the content and scope of ICOI policies at 60 research universities in the U.S. Association of American Universities. In particular, we focused on the following categories: disclosure, review, management, and prohibited or constrained activities. Most of the plans were relatively unelaborated, but 8 were elaborated "university as firm" policies that addressed the way officers and managers acting as agents for the university handled commercial activity through an array of management tools. However, even elaborated current ICOI policies may not be sufficient to manage ICOI because this type of commercial activity is not routine for universities in that faculty discovery or creation of intellectual property is not predictable. Thus, nearly all ICOI is managed on a case-by-case basis by various committees or senior institutional officials. As a result, institutional policy is only as strong as these committees and officers and the management plans they develop and monitor to handle conflicts.

KEY WORDS: institutional conflict of interest, university as firm, ethics of institutional investment in intellectual property

Received: May 15, 2009; revised July 11, 2009

TECHNOLOGY TRANSFER EXPANDS UNIVERSITIES' capacity to act more like firms and less like research and educational institutions (Slaughter & Rhoades, 2004). Consequently, university officers who make decisions about institutional income streams from intellectual property must balance conflicting goals, such as the desire to increase external revenues vs. academic integrity and human subjects' protection, creating greater potential for institutional conflict of interest (ICOI). In May 2009, in recognition of the risk to research integrity posed by ICOI, the Public Health Service (PHS) issued a call for public comment on how to define and address ICOI (U.S. Department of Health and Human Services, 2009). To better understand ICOI within research universities, we locate university ICOI within the broader literature on conflict of interest (COI) and institutional review boards (IRBs), introduce possible dimensions of ICOI, and then analyze the ICOI policies of the 60 U.S. Association of American University (AAU) universities. The AAU is an association of 60 leading public and private U.S. research institutions.[1]

Institutional conflict of interest is a growing concern for research universities. Between 1995 and 2005, over 1.5 million patents were granted to U.S. universities (National Science Foundation, 2008). As university ownership of intellectual property grew, so too did licensing income and the numbers of spin-off companies based on academic inventions. In 2005, according to the Association of University Technology Managers (AUTM), 24 universities reported earning more than $10 million from licensing income. A handful earned over $100 million. The total number of reported new start-up companies in 2005 was 404 (Blumenstyk, 2007).

Conflict of interest has been studied primarily at the level of individual researchers (Boyd, Lipton, & Bero, 2004; Bekelman, Li, & Gross, 2003; Cho et al., 2000; Van McCrary et al., 2000). Studies of COI at the institutional level have generally focused on Institutional Review Boards (IRBs) (Campbell et al., 2006; Campbell et al., 2007; Bartlett, 2008; Wolf et al., 2008; Reeser et al., 2008) and occasionally on ICOI that IRBs are asked to address, for example, when IRBs are asked to review potential ICOI by university officials who are considering making an investment in intellectual property based on faculty research that involves human subjects (Weissman et al., 2008).

COI policies focus on a variety of conflicts that may confront faculty, often concentrating heavily on ownership of intellectual property, protection of human subjects, and faculty interaction with industry. As Cho et al. (2000) point out in a study of COI policies directed

Journal of Empirical Research on Human Research Ethics, pp. 3–20. print issn 1556-2646, online issn 1556-2654.
DOI: 10.1525/jer.2009.4.3.3

largely toward faculty and research staff, including postdoctoral researchers and graduate students, increased involvement with business "has created opportunities for conflicts of interest for university faculty members because academic-industry partnerships can offer direct financial rewards to individual faculty members in the form of consulting fees, royalties, and equity in companies while simultaneously funding these faculty members' research" (p. 2204). The concern is that the promise of financial gain will consciously or unconsciously influence faculty members' research in terms of quality, outcomes, and dissemination (Krimsky, 2003). The potential for financial COI adds another dimension to concern about human subjects' protection in that researchers running clinical trials may have direct or indirect interest in the financial outcome if they hold patents on treatments, processes, or medical devices.

COI and ICOI

ICOI is somewhat different than COI, and there has been little research on ICOI. ICOI refers to situations in which research, teaching, or service are compromised because external financial or business relationships held at the *institutional level* may bring financial gain to units or the institution in form of increased revenues, whether payments or donations, or when external financial relationships have the potential to influence decision making regarding these activities. Of course, individuals may benefit as well when institutions license their patents or invest in their products. As the University of Kansas ICOI policy states:

> An institutional conflict may develop when the institution (such as a department, center or college, the applicable Research Foundation, or the University) stands to benefit financially from the outcome of research ongoing at the University to support a license or a research agreement. A Research Foundation, and/or units at the University, along with inventors, may receive future financial rewards by way of royalties or other fees if the product or service is commercially successful. Therefore, they have a financial interest in ensuring the success of the product (University of Kansas, 2007).

Administrators at the rank of department chair and above are the focus of ICOI policies. Although faculty are often the originators of intellectual property, administrators, specifically university officers, are usually the institutional actors in positions that allow them to influence or appear to influence research investments in ways that maximize individual or institutional gain, even though they are not directly involved in conducting research.

All AAU research universities now have some combination of human subjects' research policies, IRBs that administer those policies, individual COI policies, and COI committees. Many also have ICOI policies. These ICOI policies have evolved as universities have entered into greater numbers and varieties of university-industry partnerships, including industry-sponsored research, technology licensing based on patents, and investment in startup companies.

These various boards, committees and policies overlap to some degree and differ from university to university in their scope. For example, some universities have a separate COI committee to which IRBs refer apparent COIs and ICOIs to determine whether they are permissible and if so, how they are to be managed; other universities require their IRBs to identify and manage COIs and ICOIs, though some (e.g., Weissman et al., 2008) have expressed concern about whether this responsibility should be added to IRBs' already considerable workload and whether IRB members have sufficient training to be able to evaluate or manage COIs and ICOIs. At present, there are no clear federal guidelines specifying roles, so for example, IRB members surveyed on their opinions regarding investigators' relationships with industry did not agree on whether investigator-industry relationships should be considered when reviewing protocols, and among those who believed that such relationships should be disclosed to research participants, only about half of those members reported that this is done (Weissman et al., 2008). As COI scholars have pointed out, the various and overlapping policies and committees may contribute to the lack of knowledge and uncertainty about processes that many respondents to CIO surveys exhibit (Campbell et al., 2007; Weissman et al., 2008). With regard to medical schools, 25 of the 125 medical schools inform their IRBs of potential ICOI if human subjects are involved (Ehringhaus et al., 2008).

POTENTIAL DIMENSIONS OF ICOI

Potential ICOI has several possible dimensions: (1) *university as firm* in which institutional officers are economic actors who manage university technology transfer activities to maximize commercial interest; (2) *"sand and gravel"* in which an officer acts to maximize their own self-interest; (3) *exchanges* in which institutional officers engage in broad, unspecified *quid pro quo* arrangements with industry.

(1) The *university as firm* conflicts are the most recent type of ICOI and arise primarily when universities are involved in commercialization activity. This may range from sponsored research to licensing intellectual property

or holding equity positions in spin-offs based on faculty research (Krimsky, 2003;Washburn, 2005; Bozeman & Hirsch, 2005; Kavanaugh, 2009). In these transactions, institutional administrators act as corporate rather than academic managers. When university officials participate in commercialization, they become economic actors, seeking to maximize revenues. This economic goal may conflict with research integrity or human subjects' protection requirements, hence the need for ICOI policies.

Equity agreements are particularly contentious because financial markets react to information to which academic institutions have privileged access. There is the potential for researchers and university officials to manipulate share prices by withholding information or grandstanding. This potential ICOI is intensified because of the substantial value of the investment if the company is successful. Whether university officials are licensing an intellectual property or taking equity in a corporation based on faculty research or initiating an initial public offering (IPO), the economic goal is to maximize revenue and that goal may be in conflict with the goals of research integrity or human subjects protection, hence the need for ICOI policies.

University as firm conflicts may also compromise academic values of openness and sharing of scientific information. Faculty and/or graduate students may be asked to withhold or delay publication while universities acquire patent rights to intellectual property (Slaughter, Archerd, & Campbell, 2004). When universities own intellectual property, a desire for profits may lead them to restrict access to the knowledge they now own. For example, Harvard's oncomouse, licensed to DuPont, was a proprietary cancer research tool, the use of which had to be negotiated between DuPont and the Public Health Service in order to protect DuPont's investment before it became widely accessible to researchers (U.S. Department of Health and Human Services, 1999). Moreover, universities often lobby state government on legislation that restricts public access to university-industry agreements on the grounds that it would benefit competitors. However, this secrecy impedes public oversight (Slaughter & Rhoades, 2004).

The Jesse Gelsinger case illustrates a *university as firm* conflict of interest. Gelsinger was an 18-year-old man recruited to participate in a gene therapy clinical trial at the University of Pennsylvania, despite contraindications that should have excluded his participation. Gelsinger died while participating in the trial. The lead investigator, James Wilson, a professor, along with William Kelley, former medical school dean and then Chief Executive of the University's Health System, held three patents on aspects of the experimental gene therapy. These patents were licensed to Genovo, Inc., a company founded by Wilson that also provided research funding for his university laboratory. In return for the funding, Genovo had the right to develop commercial products from the research. Wilson and the University of Pennsylvania also held stock in Genovo. As Washburn (2005) points out, "[B]oth Wilson and the university stood to profit if the study was successful." And, despite Gelsinger's death, both Wilson and the University of Pennsylvania profited. Genovo was sold to a larger company, making Wilson's stock options worth $13.5 million, and the university's equity share worth $1.4 million. When faced with litigation by the Gelsinger family after Jesse's death, the University of Pennsylvania reached an undisclosed, out-of-court settlement. In this case, the institution was financially involved through its funding of research, the conduct of the clinical trial, and its investment in Genovo. While research funding and oversight of clinical trials are covered by COI policies directed primarily toward faculty and researchers, the equity investment in the firm based on faculty intellectual property created a situation in which the university could gain financially if the trials were positive. The potential of financial gain creates a conflict with objective inquiry and research integrity. University officers are in positions that give them oversight over this range of conflicting activities, which are governed by ICOI policies.

The Gelsinger case exemplifies the interplay of roles that ideal ICOI policies should attempt to target. Without James Wilson, the faculty member, there would have been no intellectual property that resulted in the creation of the firm in which the university took an equity position. William Kelley, the former medical school dean, who supervised Wilson, was listed as an inventor on three patents and was involved as both a researcher and administrator, but was apparently acting as an individual rather than an institutional representative with regard to patenting and oversight for the experimental therapy. Technology transfer officials as well as responsible senior officials acted as representatives of the *university as firm* when the University of Pennsylvania took an equity position and later when a settlement with the Gelsinger family was negotiated. It is sometimes very difficult to separate faculty roles from administrative and managerial roles, and individual roles from institutional roles. Even the best ICOI policies reflect these difficulties.

(2) *Sand and gravel.*[2] University officials have always faced the potential for *sand and gravel*, or procurement conflicts. A classic example is a vice-president for

finance who owns a business and uses their influence to steer a lucrative university contract to their business without or despite competitive bidding. The office puts individuals in a position to seek improper financial gain for themselves or their families and friends. These conflicts arise because of the individual's position as a university officer. General state COI laws for public universities cover this type of conflict. State statutes that deal with non-profit organizations cover university officials at private universities.

3. *Quid pro quo* exchanges occur when a unit within the university, or the university as a whole, has an exchange relationship with industry brokered by university managers. Through this relationship, industry provides various forms of support to the university in return for association with the university's name or university use of its products. Sometimes these relationships are contractual and clearly spelled out. At other times, they are ill-defined or tacit exchanges.

Quid pro quo exchanges frequently involve university departments or units. Campbell et al. (2006) found in their survey of medical schools and teaching hospitals, two-thirds of the departments as administrative units had *quid quo pro* relationships with industry. These relationships involved research equipment, grants of unrestricted funds, support for research seminars, support for training and residency for students, support for department-administered continuing medical education (CME), discretionary funds for food and beverages, support for professional meetings, and subscriptions to professional journals. A conflict arises because these relationships may commit the department to certain activities when other companies and products might better meet the therapeutic, educational, and even financial goals of the university.

Quid pro quo exchanges also occur at the level of the university. These exchanges are often unspecified and sometimes tacit. A donor holds out the promise of funds and university officials act in ways they think will secure them. The ICOI issue is similar to that at the department or college level: the university official(s) may act in ways that secure the gift rather than in ways that serve human subjects or the public interest. At the extreme, as in the Olivieri case at the University of Toronto, university official(s) may undermine the integrity of the research process. In this case, the Canadian pharmaceutical corporation Apotex had promised the University of Toronto a multi-million dollar gift, and the university initially did not support Nancy Oliveri, a professor and researcher, when she attempted to report negative findings about Deferipron, an Apotex product (Thompson, Baird, & Downie, 2001).

As institutions became involved in increasing numbers of academic-industry relations and these become more complex, the need to develop ICOI policies that address all three dimensions of ICOI became apparent. Associations representing research universities began to address the topic of ICOI policies after 2000. In 2008, the Association of American Universities (AAU) and the American Association of Medical Colleges (AAMC) issued a template for ICOI policies that focuses specifically on human subjects' research (Association of American Medical Colleges Task Force on Financial Conflicts of Interest in Clinical Research, 2002; AAMC-AAU, 2008). There has been commentary but little empirical study of COI or ICOI policies (McKinney & Korn, 2005). The exception is a recent survey of deans of medical schools (Ehringhaus et al., 2008). The survey focused on two key dimensions of ICOI as identified in the AAMC-AAU policy statements: "those (dimensions) created by financial interests held by the institutions and those potentially created by the financial interests of institutional officials." The study found that adoption of ICOI policies by U.S. medical schools was "far from complete on both dimensions" (p. 669). Rather than examining ICOI policies, the study queried the deans on pre-formulated questions addressing the two dimensions. Because the deans were not queried about institutional policies per se, they could respond only according to their knowledge of policies or practices, and they were not asked to distinguish between the two. This paper takes a different approach, analyzing the ICOI policies at AAU institutions on multiple dimensions to better understand the rules universities have devised to regulate ICOI. Although this type of analysis does not provide information about how specific cases at institutions are handled, it systematically reveals the procedures and tools available to administrators monitoring ICOI, and allows for comparison and assessment.[3]

Method

The sample for this study consisted of ICOI policies that we collected from the websites of the 60 U.S. AAU universities. Data were collected between September 2005 and September 2007. Because of the AAU universities' extensive involvement in commercialization, they are an appropriate group for the study of ICOI. In 2006, the 53 AAU universities in the Association of University Technology Managers (AUTM) survey constituted 23 of the top 30 institutions in terms of licensing revenue, capturing 84.5% of that revenue, and accounted for 90% of the startups in the same group (AUTM, 2006).

Although paper copies of ICOI policies identified by institutional officials may have been the preferred data source, we had difficulty obtaining such copies. Our initial efforts to identify appropriate officials and policies were unsuccessful. When we contacted officials at public universities, they often evinced lack of clarity about which ICOI policy was authoritative, while officials at private universities were reluctant to reveal any information, sometimes stating they were not required to do so because of their private status. When officials cooperated, they most frequently referred us to websites. It is certainly possible that we did not locate the right officials, but time constraints led us to decide that a search of websites would be more efficient than more telephone calls.

A web search is a justifiable way to locate ICOI policies because the Web is very likely the first place a faculty member, researcher, or institutional officer would turn to find relevant ICOI policies.[4] As the AMMC-AAU (2008) states, "Institutional COI policies should be publicized on campus and made available to the public" (p. 19). We understand that all institutions likely have policies that at the very least apply to officials in a position to benefit financially from their university posts, whether these are in state statutes governing non-profits or part of the state administrative code. Moreover, we reasoned that ICOI policies that were difficult to locate were unlikely to have a powerful impact on the persons or positions to which they were directed.

We developed a search strategy that we applied to each institutional website. The following search terms were used: *COI* or *COI policy* or *policies*; *faculty COI policy* or *policies*; *ICOI policy* or *policies, trustee/regent ICOI policy* or *policies*, or, if another term, such as *Board of Governors*, designated the oversight body that was used. Although ICOI policies were the target, we used the broader search terms to ensure that ICOI policies located at various institutional levels and sites were captured. For example, general COI policies occasionally contained material about ICOI, while faculty-directed COI policies sometimes contained language that applied to institutional officers. Similarly, trustee/regent COI policies had some language that covered institutional officers. In addition to a general search at each university, we also searched the following pages and/or websites for policies addressing ICOI: research; faculty handbook; human resources; medical school; research-medical school; and regents/trustees. If the university was part of a system, we searched for ICOI policies on the system's web pages.

As we searched the Web for ICOI policies at AAU universities, we discovered they had numerous and at times multiple policies that covered COI generally. However, our primary concern was locating and analyzing policies that regulated institutional officers involved in financial activity that could lead to potential ICOI. When reviewing a "community" policy that addressed all members of the university, some institutional officers at the level of department head or above had to be specified by office if the policy was included in our sample. Similarly, sections of faculty policies were included if "faculty and officers" were named, although we extracted data only about the "officers."

Given that more than one policy at any single university often dealt with ICOI, we typically extracted data from the policy that governed other policies. For example, a number of university medical schools had ICOI policies, as did the universities in which they were located. Within universities, various colleges and even departments occasionally had ICOI policies. When a university policy indicated that it provided the guiding framework within which other policies were articulated, that was the policy from which we extracted data. At public universities in a system (e.g., the University of California system and the University of Colorado system), the system level often provided the framework within which component parts had to operate, and then we extracted data from the system level.

We excluded policies that dealt with conflict of commitment, which we take to be "conflict over competing faculty responsibilities, e.g., whether faculty allocate more time to their traditional academic duties or their industrial sponsor" (Campbell & Slaughter, 1999, p. 311), or the many other conflicts that university policies currently address. We converted web pages to Adobe PDFs to standardize page length.

Of the 34 public institutions surveyed, 26 (76%) had publicly accessible ICOI policies on their websites. Of the 26 private universities, 18 (69%) had such policies. Two of the public institutions had 2 sets of ICOI policies, applying to different groups of officers, as did 2 of the private institutions. For example, at several institutions, one set of policies covered technology transfer officers, while another set covered "senior officers," such as vice-presidents and the president. In other words, of the 60 AAU universities, 44 (73%) had publicly accessible online ICOI policies; the 44 institutions had 48 ICOI policies. A data abstraction instrument was developed that covered topics related to ICOI, including five major categories: (1) general descriptors, (2) prohibitions, (3) disclosure processes, (4) review and management processes, and (5) other characteristics. There were 19 subcategories within these five major categories (see Table 1).

TABLE 1. Data Abstraction Items.

General
- Institution
  - Control (private, public)
- Number of policies related to institutional conflict of interest
- Effective date(s)
- Length(s)
- Covered groups
  - What positions or groups of positions (e.g., community, faculty and officers, senior officers)
- Actors: Individual actors or institution as actor

Prohibitions
(e.g., no misuse of confidential information, no directorships of private or nonprofit corporations, no clinical trials if university has licensed technology)

Disclosure
- Initiator
- About whom information must be disclosed (e.g., official, immediate family members)
- Types of interests required to be disclosed (e.g. financial interests, outside activity, equity positions, board memberships, management positions)
- To whom disclosure is made
- Decision maker who decides whether disclosed interests are a conflict
- Management
  - Person or office with final authority about conflict decisions

Review and Management Process
- Reviewer of disclosed conflicts
- Decision maker(s) following review
- Tools for managing conflicts of interests (e.g., recusal, firewall, divesting, vacating)
- Exceptions

Other
- Sanctions
- Compliance with state law
  - 20 items

Results

EFFECTIVE DATE

We located effective dates for all but 2 policies. Eleven universities established ICOI policies before 1995, 3 between 1995 and 1999, and the remainder (30) after 2000. The dates for the policies may not be reliable, in that the dates given may be the date of last revision rather than the date of initiation. Regardless of whether dates are for initiation or revision, the majority of activity for private and public universities occurred after 2000.

LENGTH

Universities' policies that addressed ICOI in community or faculty and officers policies ranged from 1 or 2 sentences to 20 pages. Private universities' policies were generally brief, the majority less than 1 page. In contrast, public universities' policies were longer, averaging 11 pages. That public universities, which frequently have well-developed bureaucratic structures and are sometimes embedded in state systems, have longer policies than private is not surprising.

COVERED GROUPS

The ICOI policies covered the following groups—the university community as a whole (community); faculty and officers; trustees and officers—or were separate policies that dealt specifically with ICOI and referred specifically to officers or managers, who could range from the level of department head to the president but were most often "senior officers." Of the 44 institutions with policies, 18 had community policies, 5 had policies that covered faculty and officers, 9 had policies that covered trustees and officers, and 12 had separate policies. Of the 8 separate public policies, 3 were directed to the university research foundations, on which the senior officers (vice presidents and above, as well as senior technology transfer officers) sat, while only 1 of the private policies was aimed at a university foundation.

While private universities generally imposed fewer prohibitions, public and private universities were more similar than dissimilar with regard to the majority of prohibitions. Both addressed *sand and gravel* issues such as prohibiting officials or managers from engaging in real estate transactions involving the institution. Both generally specified delay periods before officers and managers who terminated employment with the institution could again do business with the university.

However, there were a few notable differences in what public vs. private institutions prohibited (see Table 2). Public universities had many more prohibitions that dealt with purchasing, the use of positions to obtain political office, the acceptance of gifts and misuse of insider information than did private institutions. For the most part, these sections of the public policies read like *sand and gravel* policies directed toward public officials—in this case, using public office to secure private gain. "Outside employment" clauses were somewhat different. For the most part, they read like *sand and gravel* policies, allowing no outside employment in order to prevent managers from double dipping. However, outside employment clauses were occasionally directed toward officers acting as managers of *university as firm*, prohibiting directorship and management positions that might conflict with enhancement of the university's portfolio.

Another clear distinction between public and private universities centered on ICOI policy clauses about officers having financial interests in businesses transacting

TABLE 2. Activities Prohibited by Institutional Conflict of Interest Policies.

Prohibited Activities	Number of Institutions	Specific Limitations on Policies
Purchasing	1 (5%)	No university purchasing from business in which officer is involved
No use of position to obtain benefits	2 (9%)	No receipt of money for performing official duties (1) No benefits received from those supervised (1)
No holding of political or public office	3 (14%)	No non-elective dual office holding (1)
Outside employment	3 (14%)	No directorships of private or nonprofit entities (8) No management positions (6) No private employment for more than $4000, including nonprofits (2)
No gifts or favors No sharing of compensation No misuse of insider information	12 (57%) 2 (9%) 10 (48%)	Unless directed to museum or charity (1)
Officers having financial interests in business doing business with university	15 (71%)	No investments or income from investments (6) No loans from businesses doing business with universities (6) Delay period after termination before doing business with university (2) No interests in real property (6) No investment if they supervise the faculty (2) No real estate transactions (2)
Institution having financial interests in faculty research	8 (38%)	No university officer can be a company officer and/or hold equity in a start-up prior to IPO (3) No university officer can be a company officer (2) University cannot have representation on boards of directors (1) No pipelining of future technology (1) Foundation cannot have controlling interest in technology (1) No investment in firm by university if faculty are managers (1) University cannot be a major equity holder (1) University cannot hold more than 10% equity in a start-up company (1) University cannot be lead investor or syndicating agent if faculty research is involved (1) When institution is partner in venture fund, TTO office cannot engage in licensing agreements (1)
Institution making investment decisions that impinge on faculty research activity	3 (14%)	Institution cannot prefer technologies in which it has invested (1) Institution cannot impinge on faculty academic freedom (1)
No clinical trials if institution has equity position in product/treatment	4 (19%)	

Number of policies with explicit prohibitions = 21; number of institutions with policies = 44; number of policies = 48.

with universities. A greater percentage of private universities (6 universities, or 100%) had prohibitions than did public (9 universities, or 60%).

Universities had prohibitions about administrators or officers who represented the *university as firm* having financial interests in faculty research (see Table 2). Generally, these prohibitions centered on what officers and administrators representing the *university as firm* were prohibited from doing when seeking to expand revenue streams from the university. For example, they specified the following provisions:

- Technology transfer officers were prohibited from engaging in licensing agreements when the institution was a partner in a venture fund.
- Universities were prohibited from investing in firms in which faculty were managers.
- Universities were prohibited from being the lead investor or syndicating agent if faculty research was involved.
- Universities were prohibited from holding more than 10% of equity in a faculty startup company.
- University officers were prohibited from being company officers or from holding equity prior to an IPO.

- Officers and managers were prohibited from investments in companies if they supervised faculty members who started such companies.

The universities also had a number of prohibitions about investment decisions that impinged on faculty research activity. These prohibitions focused on universities not making decisions about technology investments or upstream investments that committed the universities financially to technology lines if such commitments could in any way potentially jeopardize the opportunity for faculty exploring alternative research leading to competing technologies.

Four universities had prohibitions against clinical trials if the institutions held equity positions in a product or treatment. Three private universities (50%) had such a provision compared to one public university (6%). The provisions were aimed at preventing potential ICOI or the appearance of potential ICOI when institutional officers and managers acting for the *university as firm* stood to have the institution benefit from successful trials. These policies specifically addressed the conduct of clinical trials for products from university equity startups. Some policies prohibited any clinical trials under these circumstances while others stipulated procedures at different stages of the clinical trial.

Although a number of AAU universities' ICOI policies had clearly articulated prohibitions, they also had specific language in their policies that created exceptions to the prohibitions. For example, policies that prohibited universities from taking equity positions in products or treatments when university researchers were running clinical trials nonetheless usually had provisions that outlined circumstances in which the universities could take such positions despite the prohibition. For example, exceptions could be made if the particular institution was the lone facility with the scientific expertise to conduct a study, or if the public interest was best served by running the trials at the institution. Explicit language about exceptions may make recognition of exceptions more likely. Exceptions to prohibitions and disclosure processes will be more fully discussed below.

DISCLOSURE

Of the 44 institutions with ICOI policies, 37 (84%) required that officers and administrators disclose financial interests that might create conflicts. In the policies requiring disclosure, individual officers or administrators initiated the disclosure process, generally by filling in ICOI forms annually, or if their situation changed and a potential new conflict emerged, updating the form. Only two policies, both at public institutions, called for institutional committees or staff to proactively monitor for potential problem areas likely to trigger disclosures. In these policies, institutional committees or COI staff were required to scan university investments—particularly equity—corporate gifts, donations and research funding, technology transfer activity, and research involving human subjects to determine whether universities and/or faculty were investing based on university-owned/faculty-discovered intellectual property, or if corporations were funding research in areas in which the institution or faculty had commercial activity or were conducting research on human subjects. The committees or COI staff then alerted faculty and officers about potential dangers, in case they had missed them. However, there was no discussion of follow-through after the alert.

Generally, the policies required the individual, whether faculty, officer, or administrator, to disclose not only their financial interests, but also the financial interests of immediate family members (parents, spouse, and children) in any business that did business with the university, whether that business had contracts with the university for goods and services, or whether the business involved technology transfer. These policies were *sand and gravel*, directed at preventing officers and managers from using family members with whom they shared finances to acquire inappropriate interests in university businesses.

Disclosure entailed revealing financial interests, covering a wide range of activity, ranging from investments to positions on external boards (see Table 3). Sixteen public and 9 private universities specified financial interests to be disclosed by institutional officials and managers in the ICOI policies. The 16 public universities had a wide range of monetary activity that triggered disclosure—from holding more than $500 or 5% interest in a business or 3% in an equity company to $20,000 or 5% interest in an entity. The private policies had a similar range, but were more nuanced, specifying different types of investments and activities, with the range starting slightly higher than the public's, with the exception of 1% of securities. The same number of public and private universities asked officers and managers to disclose partnerships, managerial positions, and trusteeships. Neither consulting nor outside activity were clear triggers for disclosures. A single public university required that the institution *qua* institution disclose if it had invested more than $100,000 or had a 5% interest in a company.

Although only 26 of the universities (59%) specified what financial interests and activities triggered disclosure by officers and mangers in ICOI policies,

TABLE 3. Disclosures of Financial Interests and Activities.*

Public Universities	**16**
Business or financial interests	
More than $500	1
$2,000 interest in business, or 5%	6
5% ownership of business	1
$10,000 interest in business, or 5%	1
$10,000 interest in business, or 3% in equity	1
10% interest in business or personal interest	1
$20,000, or 5%	2
Significant financial interest	3
Partnerships, managerial positions, trusteeships	3
Outside employment	2
Institutional investment	
$100,000, or 5% of entity	1
Private Universities	**9**
Business or financial interests	
1% securities, 10% partnerships, or 5% assets	1
$10,000 interest in business, or 5%	3
10% interest in business	2
$25,000 interest in business, or 5% of public company, 10% of equity	1
Equity	1
Partnerships, managerial positions, trusteeships	3
Outside employment	1
Consulting	1

*Of 44 universities with 48 policies, 25 institutions addressed what financial activity institutional officers and managers were required to disclose. The numbers beneath the sum (public 16, private 9) do not add up because a number of policies required more than one activity to be disclosed.

disclosure may be dealt with elsewhere in university documents. Even if officers and managers were not specifically mentioned in the ICOI policy, they nonetheless may be expected to fill in disclosure forms, which are usually separate from the policies. These forms, often available on the Web, covered more employees than those named in the policies, were very detailed, and may have had many more disclosure triggers than those in ICOI policies.

Disclosures were most often made to and reviewed by senior officers or university boards of trustees or regents and were quite similar for public and private universities (see Table 4). Nineteen (40%) of the policies required disclosure to be made directly to senior officers or members of boards of trustees/regents. If the 5 policies in which disclosures were made to legal counsel, university officers, and/or boards of trustees and regents, and the 2 in which disclosure was made to senior officers and/or system senior officials are combined with the disclosures made directly to senior officers or members of boards of trustees/regents, then 54% of the policies called for disclosure to and review by high-ranking officials, or high-ranking officials and senior legal counsel. Very few made disclosures to an ICOI committee.

After disclosure and review, decisions about management plans were sometimes made if conflicts were identified. The officials or committees that made the plans were quite similar to those who received and reviewed the disclosures (see Table 4), except that there were fewer in the "other" category and significantly more (8, or 17%) that employed an ICOI committee that worked with senior officials and/or boards of trustees and regents. More private universities (5, or 25%) used this process than public ones (3, or 10%).

Final authority over the disclosure process was highly concentrated. "Other" officials and committees dropped out and, if senior legal counsel, senior university officers, and boards of trustees/regents are combined with senior officers and board members, 34 policies (72%) conferred authority at the highest levels of the university and/or its oversight board (see Table 4).

The disclosure process makes clear that ICOI policies focused on senior-level officers, who disclosed either to those immediately above them (dean to provost, provost to president, president to trustees) or to each other (technology transfer officers to vice-presidents; vice-presidents to provost or president, depending

TABLE 4. Disclosure Process: Receipt and Review.

	Receipt and Review	Decision on Management Plan	Final Authority
Immediate supervisor	4 (8%)	2 (4%)	
Institutional COI committee	3 (6%)	2 (4%)	
Senior university officer and/or board of regents or trustees	19 (40%)	20 (42%)	32 (67%)
Legal counsel and university officer and/or board of regents or trustees	5 (10%)	3 (6%)	2 (4%)
Senior officer and/or senior system official	2 (4%)	1 (2%)	
Legal counsel	2 (4%)	1 (2%)	
Other	8 (17%)	3 (6%)	6 (12%)
Unspecified	5 (10%)	8 (17%)	
COI committee and senior officer or board of regents or trustees	0	8 (17%)	8 (17%)

on the lines of authority; provost or chancellor to presidents; and presidents to senior system officers). The focus on administrators and senior officers underscores the individual and institutional potential for ICOI at high levels. When the individual is the target, the policies focus on *sand and gravel* potential for ICOI, in which an individual can use their position to enhance business opportunities inappropriately. When the *university as firm* is the target, the policies are aimed at managers and officers with the authority to act as agents for the institution, seeking to prevent them from enhancing revenues at the expense of the university as a community, at the expense of human subjects, or at the expense of the public good, as well as to prevent inappropriate commercial activity.

MANAGEMENT PLANS

Although over three-fourths of the ICOI policies called for disclosure on the part of administrators and senior officers, approximately half of these policies (49%) did not discuss how management plans would be developed to manage conflicts that were identified. More private university policies (11, or 55%) lacked plan specifics than public ones (11, or 39%; see Table 5), but otherwise the management tools were quite similar.

Recusal was the most commonly named management tool. A greater percentage of private universities (16, or 80%) relied on recusal than did public ones (21, or 75%). In most policies, recusal meant that the managers or officers with financial interests in decisions had to absent themselves from the decision-making process. However, in some instances, managers and officers were able to present their views on financial decisions to the decision makers prior to the decision. In other words, managers and officers could be heard, although they could not participate in voting.

Other management tools appeared in 7 or fewer (14% or less) of the policies. Creating a firewall between officers and managers who handled investments and those who managed technology transfer or endowments was a tool for managing potential conflict, as were using arms-length organizations or freezing or sequestering institutional investment. If faculty, administrators, or officers were in a situation with a high potential for ICOI, such as investment in a start-up engaged in clinical trials, divesture, vacating management positions, and resiting trials were tools that could be used to minimize conflict. Disclosure of the scope of individuals' and institutions' financial interest in the products, treatments, or processes to the human subjects involved in clinical trials was also a means of managing ICOI. Several private universities saw independent external review committees as a way to handle conflicts, and one private university called for a review of adverse advents.

In sum, the majority of universities called for disclosure but did not specify management plans or tools. Approximately half the policies did not discuss how plans to manage identified ICOI should be developed. Although the ICOI policies in aggregate provide an array of tools for managing conflicts, most universities deployed only one to three in their policies.

EXCEPTIONS

Eleven (55%) of the 20 private university policies had language in their institutional policies that provided for exceptions to prohibitions and disclosure processes, as did 11 (39%) of the 28 public university policies. A number of policies had multiple exceptions. The exceptions

TABLE 5. **Tools Potentially Used to Manage Disclosed Institutional Conflicts of Interest.**

	All = 48	Private = 20	Public = 28
Disclosure to institution	37 (77%)	16 (80%)	21 (75%)
Unspecified beyond disclosure	22 (49%)	11 (55%)	11 (39%)
Recusal	12 (25%)	2 (10%)	11 (39%)
Firewall	7 (14%)	2 (10%)	5 (17%)
Disclosure to human subjects	6 (12%)	2 (10%)	4 (14%)
Divestiture	5 (10%)	3 (15%)	2 (7%)
Vacating management position	3 (6%)	0	3 (11%)
Independent external review	3 (6%)	3 (15%)	0
Freezing or sequestering institutional investment	2 (4%)	2 (10%)	0
Arms length organizations	1 (2%)	0	1 (3%)
Review of adverse events	1 (2%)	1 (5%)	0
Resiting	1 (2%)	1 (5%)	0

Number of institutions = 44; number of policies = 48.
Of 44 universities with 48 policies, no institution engaged in all the methods used to manage disclosed conflict of interest; therefore the numbers beneath the sum (private = 20, public = 28) do not add up because most universities had few methods of management.

ranged from allowing acceptance of gifts in certain circumstances to allowing university investment that breached firewalls. Regardless of prohibitions, decisions about how to manage ICOI were made on a case-by-case basis.

SANCTIONS AND COMPLIANCE WITH STATE LAW

Private university policies did not mention sanctions for violation of ICOI policies explicitly, although two policies mentioned complying with state law with regard to ICOI. In contrast, 11 public institutions (42%) mentioned sanctions in their policies and 20 (77%) indicated that they would comply with state law in regard to ICOI. The sanctions ranged from administrative sanctions through civil and criminal ones. For the most part, the sanctions were not elaborated. Generally, state laws were not specified, but occasionally the name and number of the law were provided.

Discussion

We posited three possible categories of ICOI policies—*sand and gravel*, *university as firm*, and *quid pro quo*—prior to our analysis. After conducting our analysis with regard to the degree of coverage of conflict situations, we revised our categories to the following four policies: *minimal* policies; *sand and gravel* policies; *modestly elaborated university as firm* policies; and *elaborated university as firm* policies. *Minimal* policies were very short, usually only several sentences, focused on individual administrators rather than the institution, and had no more than one management item, such as to whom disclosures are made or what is disclosed. Of the universities with policies, 7 private universities (39%) had minimal policies, as did 5 public universities (19%). Universities with *sand and gravel* policies had several prohibitions and/or management tools, but focused on managers and officers as actors who may violate ICOI by maximizing individual gains. Five private universities (28%) had *sand and gravel* policies, as did 9 public universities (35%). *Modestly elaborated university as firm* policies regulated the activities of managers and officers acting not only for themselves but also as institutional executives seeking to maximize university commercial activity. Although these policies recognized that managers and officers made decisions that committed the university as an institution to strategic investment decisions with the potential for ICOI, they did not have well-specified tools for managing such conflicts. Two private universities (11%) and 7 public universities (27%) had such policies.

Elaborated university as firm policies regulated the activities of managers and officers acting for the *university as firm* through a variety of specified management tools. Three private universities (17%) had such policies, as did 5 public institutions (19%). The 8 elaborated policies were all separate policies, although not all 12 separate policies were elaborated. Two of the elaborated public policies dealt with university foundations that managed technology transfer on which senior officers of the institutions sat as managers.

Quid pro quo policies did not figure in AAU ICOI policies.

Taken together, the procedures and management tools articulated in the elaborated policies brought together some of the building blocks that might provide a comprehensive approach for regulating ICOI for the university as firm. (Most of the prohibitions [Table 2], and tools for managing disclosed ICOI [Table 5] were drawn from the elaborated policies, and may be reviewed for details.) Among the building blocks are the following:

- Disclosing to equity review committees, ICOI committees, external review committees, and to the public, professional associations, scientific journals, and human subjects;
- Options other than individual initiation of disclosure;
- Close regulation of officers and managers when investments were made in faculty intellectual property;
- Management tools that went beyond recusal, including creating "arms-length" distance between managers engaged in activities such as technology transfer, fund-raising, investment and other financial decisions through firewalls, vacating, divesting, resiting, sequestering, freezing institutional involvement, creating independent external review committees when human subjects participated in clinical trials, and reviewing adverse events.

EMPLOYMENT OF STUDENTS

A single institution, one with elaborated policies, addressed the work practices and employment of graduate students when discussing management of ICOI. This public institution took the position that when the research foundation had an equity interest, it must monitor the situation with a management plan that attended to resource allocation, employment practices, and graduate student assignments. Management plans were required to be placed in individual personnel files and maintained for three years. The goal of the plan was to ensure that the graduate student was treated as a student with an array of learning opportunities rather than as a worker in an enterprise from which the university would benefit. The plan tried to ascertain whether graduate

students were fairly compensated, they worked reasonable hours, and they had assignments that fostered their education. (For faculty concerns about the problems that arise when graduate students are employed on projects in which faculty and university have financial interests, see Slaughter et al., 2002).

MATERIAL TRANSFER AGREEMENTS

Although the elaborated policies cover many of the current commercialization activities in which universities engage, there is little mention of material transfer agreements (MTA), which govern the transfer of tangible research materials when the recipient intends to use the material for research purposes. The most frequently transferred materials are biological, such as reagents, cell lines, plasmids, and vectors, but MTAs may also be used for other types of materials, such as software or chemical compounds. The potential of financial gain has created a formal review process of each request. Each agreement has provisions to govern confidentiality, publication delay, and control of intellectual property (Mirowski, 2008). MTAs are generally handled by university legal counsel and technology transfer offices, and are infrequently incorporated in ICOI policies. However, transferring materials between organizations, which may be competitors in both a scientific and financial sense, creates a potential for conflict.

ICOI MANAGEMENT TOOLS

Although the elaborated plans had a number of tools for managing ICOI, monitoring of the management plans was not widely discussed—an internal audit of a random sample of plans was mentioned in only a single instance. Sanctions were not elaborated, although they were mentioned in half of the elaborated plans, mainly at public institutions. None of the policies addressed continuing education, despite the rapidly changing commercial environment in which managers and officers of research universities operated.

Only 8 of the AAU universities had elaborated ICOI policies that used a range of management tools, and none of these used the full panoply. As Table 6 indicates, while a majority of the AAU universities with ICOI policies required that officers and managers disclose activities with the potential for ICOI, less than half specifically prohibited officers and managers from engaging in activities likely to lead to ICOI and less than half had management plans that offered tools to deal with identified ICOI. A considerable number of institutions specified exceptions to prohibitions and a relatively small number of universities articulated sanctions. As Cho et al. (2000) noted with regard to faculty, the policies we analyzed with regard to ICOI varied widely among institutions and many lacked specificity with regard to the types of relationships with industry that were allowed or prohibited.

MULTIPLE ROLES

In a number of the ICOI policies, the lines between faculty, individual managerial, institutional, and trustee conflicts of interest were blurred. While these various categories of employees overlap, given that faculty are sometimes institutional managers and occasionally managers of firms, ICOI policies often do little to clarify the ways in which conflicting statuses may exacerbate conflicts.

COMPLEXITY OF CASES AND FALLIBILITY OF POLICIES

Although ICOI policies are important, they may not be sufficient to handle all of the issues raised by ICOI at research universities. As Bozeman and Hirsch (2005) pointed out in their study of the Johns Hopkins lead paint case, "the greater the complexity of the social phenomenon, all else being equal, the greater the fallibility of the rules" (p. 82). They argued that the Hopkins' IRB had technical scientific sophistication but was not able to deal with all of the ethical implications of different levels of abatement of lead paint in houses inhabited by young children in poor neighborhoods in Baltimore, which led to IRB approval of a research design in which some young participants' lead blood levels went up due to the type of abatement assigned. ICOI decisions are certainly as complex as the IRB decisions made in Johns Hopkins lead paint case, but may be more difficult to monitor because they are usually not made in as public a forum as an IRB.

INTEGRITY OF SENIOR OFFICERS

Because of the non-routine nature of commercial activity at research universities, all ICOI is managed on a

TABLE 6. Summary of Institutional COI Policies.

	Schools	Policies	Disclosures	Prohibitions	Exceptions	Management Tools	Sanctions
Public	34	26 (76%)	21 (62%)	15 (44%)	11 (32%)	11 (32%)	11 (32%)
Private	26	18 (69%)	16 (61%)	6 (19%)	11 (42%)	11 (8%)	2 (8%)
	60	44 (73%)	37 (62%)	21 (35%)	22 (37%)	22 (37%)	13 (37%)

case-by-case basis. That means institutional policy is only as strong as the various committees or senior officers responsible for developing and monitoring management plans to handle conflicts. ICOI committees, when universities have them, are usually somewhat different from IRB committees, but IRB committees nonetheless offer insight into conflict management. As Campbell et al. (2007) recently found, 15.1% of surveyed IRB members at research universities reported that at least one protocol came before the IRB sponsored by a company with which they had a relationship or a competitor company, and that 19.4% of the conflicted board members voted on the protocol regardless. ICOI committees responsible for monitoring conflicts may find similar difficulties as research universities become more involved in commercialization. ICOI policies can be no better than the committees or officers and managers that handle them. Creating an organization culture attuned to ICOI issues may be as important as developing ICOI policies.

However, there are two problems with creating an organizational culture attuned to ICOI. First, ICOI policies, as this study reveals, are directed primarily toward high-ranking officers and managers. IRBs and faculty are generally not the focus of ICOI policies. These high-ranking officers and managers are not accustomed to close regulation, and indeed would undoubtedly claim they required discretion and authority to make independent investment decisions for successful returns. Even when *elaborated university as firm* policies provided tools for management plans, for the most part, senior officers and managers disclosed only to each other, and/or to boards of trustees or regents, raising the question of who is governing the governors. Second, when ICOI policies address officers and managers acting as agents for the university as firm, institutions may not want elaborated rules controlling investment in intellectual property that may constrain the ability to expand external revenues.

Best Practices

It is possible to approach best practices from a reasoned position, as well as drawing on some of the management tools in the elaborated ICOI policies. Conflict of interest is difficult to avoid or eliminate, but it may be managed.

TRANSPARENCY

The increasingly dense, complex relationships between research universities and industry make the case for transparency. Information about university investments in commercial firms and financial interdependencies between private research sponsors, donors, and those who stand to benefit from university activity decreases the likelihood and/or appearance of ICOI. University trustees, regents, and advisory board members are often selected because they work with or represent corporations that have interests in industrial sectors salient to universities, e.g., biomedicine, and already have ongoing complex relationships with the university or because they are in a financial position to be donors. In other words, the stewards of the universities stand a good chance of being interested parties when it comes to research and institutional investment.

The best practice would be to provide publicly available information on potential conflict situations so that it is possible to monitor them. Transparency as a practice fits well with increased public concern about financial regulation following the 2009 crisis of the global financial system. An annual listing of company investments in institutional intellectual property, whether patents, copyrights, or trademarks, that provided the names of products, processes, and services, and intellectual property details, such as licensing terms, would be a solid step towards transparency. Such a practice would allow individuals, units within universities, officials, and senior management as well as the university community as a whole to assess quickly potential ICOI if they pursue commercial activity as individuals employed by a university or if they act as agents for the university as firm. Human subjects, the public, undergraduate and graduate students, as well as any other interested parties could also access and assess the commercial endeavors of research universities. Such a practice would address the Association of American Medical Colleges–Association of American Universities (2008) concern that "[T]he existence (or appearance) of such [ICOI] conflicts can lead to actual bias, or suspicion about possible bias, in the review or conduct of research at the institution. If they are not evaluated or managed, they may result in choices or actions that are incongruent with the missions, obligations, or values of the university" (p. 1).

Transparency could reduce the potential for ICOI without burdensome oversight. Public posting of universities' investments would be a relatively efficient and effective bureaucratic process. Individual faculty, managers, and officers' disclosures could be quickly and easily checked against public postings; recursively, the public postings would alert individual faculty and officers to areas of concern, causing them to examine carefully their interests in these areas. When faculty and managers, whether acting as individuals or acting as agents of the *university as firm* have interests in these areas, they would automatically be referred to an independent,

external ICOI committee (see below). Universities already collect the information required for public posting, so existing institutional procedures and offices would be utilized. The only extra steps required would be consolidation and posting of the information, as well as checking it against disclosures.

Research universities may be uncomfortable with public scrutiny of institutional commercial activity and may make the case that posting such information regularly and publicly might damage university-industry relations. If research universities do not accept public posting of commercial investment and endeavor, then the next best practice may be to shift some of the burden for reporting ICOI from individuals to the institution. Two of the elaborated ICOI policies called for institutional committees or staff to monitor proactively for potential problem areas by scanning university investments, corporate gifts, donations, and research funding, as well as technology transfer activity, with an emphasis on institutional equity investments and research involving human subjects. As with public postings, when faculty and managers, whether acting as individuals or acting as agents of the *university as firm* have interests in these areas, they would automatically be referred to an independent, external ICOI committee.

SEPARATION OF FUNCTIONS AND DUTIES

The best policies call for the separation of officers and managers who handle investments from those who manage technology transfer or endowments. Several of the elaborated ICOI policies deal with separation through external management of investments. In other words, an entity independent of the university handles investment portfolios so that the university staff neither makes nor influences individual security transactions. This type of separation typically addresses *sand and gravel* ICOI rather than *university as firm* conflicts. *Sand and gravel* policies focus on the individual officer who might use their position for self-dealing. In contrast, *university as firm* policies address the group of officers or managers making business decisions about intellectual property and how it may be used to increase external revenues for the university. The difference is similar to that between stockbrokers who direct investors toward businesses from which they stand to gain and venture capitalists representing their firm who take risks with firm funds for high returns; the firm, in this case, the university rather than the individual, is the direct beneficiary. Separation is further complicated in that a university officer may simultaneously have both individual or *sand and gravel* and institutional or *university as firm* conflicts.

The potential for conflict for individual investment managers is eliminated by a firewall between the investment manager and persons who handle technology transfer activities or human subjects, because the investment manager, separated from the persons who deal with technology property or human subjects, cannot take advantage of any special or insider knowledge about university intellectual property. However, investment management by individuals occurs after investments have been made. What is at issue and is often the source of conflict for officers and managers acting as agents for the *university as firm* are collective decisions about institutional intellectual property that risk institutional funds for future income. Because the future of the investment is uncertain and the process of realizing the return often lengthy and complicated, with multiple decision points, the likelihood and nature of conflict is unclear. For example, university officers acting as agents of the *university as firm* have very likely already patented and taken equity in a drug discovered by a faculty member before decisions are made about running clinical trials. Milestones may have to be reached, more university funds may need to be committed, and decisions about more research funding made before the process is complete, with each decision point raising the possibility of ICOI, especially if ICOI is considered as involving not only human subjects but research integrity and university values. For example, the university may decide not to run clinical trials itself, but may continue to accept and commit funds to research even though successful commercialization is increasingly unlikely, using funds that could have been used more productively in other areas, from research investment for other commercial purposes to research investment for social purposes that may not realize investment returns but that would fulfill the university mission to serve the public good. Income from managerial decisions made for the *university as firm* may not enter the university's portfolio, where protection from ICOI is ensured by a firewall, for years, but in the interim, university managers may face many potential conflict situations.

Although all of the elaborated policies call for firewalls, most of them simply assert separation of functions and duties and do not detail how this will occur. Nor does the separation of functions and duties address the question of who supervises the supervisors. Separation of functions usually occurs below the level of president/chancellor, who are at most institutions *ex officio* members of the boards of trustees/regents. These senior

officials and fiduciary officers act together on financial decisions and are not accountable to any outside party. Yet about 25 percent of president/chancellors sit on corporate boards, and some sit on multiple boards (Goldschmidt & Finkelstein, 2001); the majority of private-sector trustees are corporate CEOs and directors of other corporate boards, many of whom have interests in universities' research areas (Slaughter, Feldman, & Thomas, forthcoming). As Ehringhaus et al. (2008) note in their survey of medical school deans, "Of the [35] institutions reporting the use of separate foundations for investment management purposes, licensing/technology transfer purposes, or both, 29 (56%) report that senior institutional officials, (i.e., president/chancellor, provost/vice chancellors/deans) serve on the governing boards of such separate entities and 18 (35%) report that midlevel officials serve on such boards" (p. 669). The purpose of the separate foundation may be to create a firewall, but in many cases officials and managers who have may have strong financial interests in the investment, licensing, or technology transfer decisions to be made are on the wrong side of the firewall. The potential for ICOI at this level is both *sand and gravel* and *university as firm*. An official or trustee could act individually on eminent investment decisions by universities to enhance individual worth, or officials and trustees could act collectively to invest in research with the potential to increase external revenues in areas which the corporations they represent have or could have interests.

TRIGGER POINTS

Best practice policies are clear about the triggers for ICOI. These include: university ownership of intellectual property or investment in areas in which the institution is running clinical trials or otherwise involving human subjects; universities taking equity positions in faculty/institutional companies; universities allowing financial or other interests to influence which technologies are selected for commercialization, who receives licenses, or the structure of licenses; universities accepting corporate sponsorship or gifts for research in areas in which the institution has made an investment or in which the institution partners with the corporation. One university suggested that if these triggers are present, an external ICOI committee composed of persons sophisticated in financial matters with an affinity for the institution, but whose financial interests are not dependent on it, form an independent committee to ensure that any research undertaken in a trigger area have no greater risk to research integrity or human subjects than comparable studies. This external committee would work with the board of trustees, the IRB, and appropriate institutional officials to provide oversight of research projects with identified ICOI.

COVERED INSTITUTIONS

For the most part, the best practices described here are appropriate for research-intensive universities. These institutions already gather much of the information discussed in the Best Practices section (above) and have institutional offices and procedures that already address COI or are skilled at constituting internal and external committees to address specific issues such as ICOI. Non-research intensive universities that do not have technology licensing offices, or hold large intellectual-property portfolios would probably be able to best address ICOI through public posting (discussed earlier), a task that would not be burdensome until such universities had large intellectual portfolios—at which point they might reconsider their procedures and policies.

Research Agenda

This project studied only ICOI policies, not how ICOI is handled within universities. While there are a number of studies of ICOI cases, for the most part, these focus on very public ICOI failures (Thompson, Baird, & Downie, 2001; Krimsky, 2003; Washburn, 2005; Bozeman & Hirsch, 2005). Several possibilities for research prior to public mishaps are possible. For the long term, universities could agree to embed researchers in institutions who could study how university managers and officers make ICOI decisions over time through participant-observation supplemented with interviews. For the shorter term, researchers could study NIH listings of adverse events to see if and how they are related to the ICOI policies at the institutions at which they occur. Another path would be an analysis of legal cases in which ICOI was involved, since cases are often fact-rich and court decisions shape ICOI policies, although potential in this area is somewhat limited, given that many universities settle these issues out of court, leaving no public record (Kavanaugh, 2009). And of course, surveys of faculty, administrators, and officers with the potential to be involved in ICIO are very useful.

Educational Implications

Senior managers and officers of universities would very likely benefit from education about their legal, ethical,

and fiduciary responsibility when they act for the *university as firm*. University retreats might be a venue for such educational activity. A range of experts could be brought in to explore the ICOI situations that senior managers and officers may encounter, and to work through various solutions. Special emphasis should be given to the differences between *sand and gravel* and *university as firm* ICOI. The issues surrounding *quid pro quo* exchanges, which are not yet part of ICOI policies, should be considered. Attention should be given to the way ICOI intersects research integrity and university values, rather than concentrating only on human subjects' research. Continuing education modules should be developed and required for mid-level managers, given the changing regulatory and legal environment pertaining to ICOI. As with much medical and legal continuing education, these modules could be offered via the Internet, through tapes, at conferences, or retreats. However, given the complexity of the issues and that ICOI is still in a nascent stage, education would probably be most successful in face-to-face forums. Care should be taken that the ethics and values of science and of the university are embodied in ICOI considerations; legal considerations alone are not sufficient to safeguard the integrity of scientific research with regard to conflicts of interest.

Acknowledgments

This work was supported by funding from NIH/National Institute of General Medical Sciences (1RO1GM080071-01A1) and the Institute for Higher Education at the University of Georgia. I am grateful to anonymous reviewers for their helpful comments on this manuscript.

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End Notes

[1]The AAU, founded in 1900 to advance the international standing of U.S. research universities, focuses on issues important to research-intensive universities, such as funding for research, research policy issues, and graduate and undergraduate education. Membership is by invitation only. There are two Canadian members, but we did not consider them because they are regulated by different sets of laws and practices. The list of AAU universities can be found at www.aau.edu.

[2]*Sand and gravel* refers to procurement conflicts that face many state officials who have fiduciary responsibilities. The term *sand and gravel* derives from stories about state officials in charge of state roads and highway programs who also owned (or their wives and/or children owned) sand-and-gravel businesses and used their position to steer lucrative contracts to the businesses. *Sand and gravel* policies cover self-dealing, and *sand and gravel* COI is often incorporated in state codes. Such policies are frequently often not sufficiently sophisticated to handle conflicts that arise when the institution, rather than the individual, benefits from investments in intellectual property designed to bring in external revenue.

[3]In the best of all possible worlds, we could study systematically cases of ICOI at research universities and see how ICOI policies influenced or shaped outcomes and vice versa. However, it is often difficult to obtain information on ICOI cases at institutions because of rules dealing with confidential personnel information, problems in gaining access to public/private partnership information, difficulties in identifying ICOI cases until after the fact, and the secrecy surrounding litigation.

[4]Of course, universities may not use public portals for such documents; rather, they may be located on password-protected sites. However, password-protected sites defeat the transparency that allows the public to understand how ICOI policies work.

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